

STEPHANIE M. HINDS (CABN 154284)
United States Attorney

THOMAS A. COLTHURST (CABN 99493)
Chief, Criminal Division

JEFF SCHENK (CABN 234355)
JOHN C. BOSTIC (CABN 264367)
ROBERT S. LEACH (CABN 196191)
KELLY I. VOLKAR (CABN 301377)
Assistant United States Attorneys

150 Almaden Boulevard, Suite 900
San Jose, California 95113
Telephone: (408) 535-5061
Fax: (408) 535-5066
Kelly.Volkar@usdoj.gov

Attorneys for United States of America

UNITED STATES DISTRICT COURT
NORTHERN DISTRICT OF CALIFORNIA
SAN JOSE DIVISION

UNITED STATES OF AMERICA,

Plaintiff,

v.

RAMESH "SUNNY" BALWANI,

Defendant.

) Case No. 18-CR-00258 EJD
)
) UNITED STATES' OPPOSITION TO
) DEFENDANT'S MOTION TO RECONSIDER
) ORDER DENYING MOTION TO STRIKE
) PORTIONS OF SARAH BENNETT'S
) TESTIMONY
)
) Date: June 13, 2022
) Time: 10:00 a.m.
) Court: Hon. Edward J. Davila

1 The government opposes Defendant Ramesh “Sunny” Balwani’s Motion for Leave to File
 2 Motion for Reconsideration of Order at Dkt. 1483. ECF No. 1487.¹ Defendant seeks leave to file a
 3 “Motion for Reconsideration of Order at Dkt. 1483” (“Motion to Reconsider”). ECF No. 1487-2. The
 4 Court’s Order at ECF No. 1483 (“Order”) denied a motion to strike portions of testimony from Sarah
 5 Bennett, who testified on May 3, 4, and 10, 2022. ECF No. 1483.² Because the Court correctly
 6 overruled contemporaneous objections to Ms. Bennett’s testimony on the same bases raised in the
 7 present motion and correctly denied the motion to strike that testimony, and because Defendant raises no
 8 new factual or legal support, the Court should deny leave to file any motion for reconsideration or
 9 simply deny the motion for reconsideration.

10 Typically, motions to reconsider are entertained in this District only when new material facts or a
 11 change in law has occurred. *See, e.g.*, N.D. Cal. Civil L.R. 7-9; N.D. Cal. Crim. L.R. 2-1 (in criminal
 12 cases courts look to civil rules so long as consistent). Indeed, the District’s Civil Local Rules, which
 13 occasionally apply to criminal proceedings, expressly prohibit “repeat[ing] any oral or written argument
 14 made by the applying party in support of or in opposition to the interlocutory order which the party now
 15 seeks to have reconsidered.” N.D. Cal. Civil L.R. 7-9(c). Here, Defendant merely reiterates his prior
 16 oral argument that there was an insufficient link for agency purposes to him based on testimony that
 17 Dr. Kingshuk Das gave during the trial of his co-Defendant Elizabeth Holmes last fall (“*Holmes* trial”).
 18 *Compare* Motion to Reconsider at 4–7, with 05/10/2022 Trial Transcript (“5/10 Tr.”) at 5095:12–
 19 5107:1. The Court considered and rejected Defendant’s argument in issuing its Order, and no new or
 20 materially different facts are presented in Defendant’s Motion to Reconsider, and thus—for that reason
 21 alone—the Court should deny Defendant leave to file his Motion to Reconsider.

22
 23
 24 ¹ Defendant filed the present motion for leave on Saturday, June 11, 2022, at 12:13 p.m., and requested a
 25 hearing for Monday, June 13, 2022, at 10:00 a.m. ECF No. 1487-2 at 2. The government is unavailable
 26 at the noticed time for hearing on this topic and submits that the Court can decide this issue on the
 papers. If the Court is inclined to hold a hearing, the government respectfully requests the hearing be
 scheduled for Monday afternoon (preferably by Zoom).

27 ² Defendant does not seek reconsideration of the Court’s alternative holding that Ms. Bennett’s
 28 testimony is relevant and thus the testimony could be admissible for the non-hearsay purpose of notice
 to CMS. Motion to Reconsider at 4 n.1. Therefore, the government does not include its arguments in
 support of that portion of the Court’s Order in this filing.

1 The Court should deny Defendant's Motion to Reconsider because it ignores both key facts
 2 elicited during *this* trial that sufficiently demonstrate an evidentiary basis under Federal Rule of
 3 Evidence 801(d)(2) ("Rule 801(d)(2)") and, even if the Court were to look to Dr. Das' testimony from
 4 the *Holmes* trial, reviewing his testimony in full context also supports such a basis for the challenged
 5 statement, as does other available evidence.

6 **First**, the evidence admitted during this trial, before this jury, supports the Court's finding of an
 7 agency relationship, or authorized or adopted admission, for purposes of Rule 801(d)(2). Several
 8 witnesses testified that Defendant was in charge of running the CLIA lab during the late 2013 to late
 9 2015 time period that Ms. Bennett was reviewing in the fall of 2015. *See, e.g.*, 03/22/2022 Trial
 10 Transcript at 1121:1–8; 03/23/2022 Trial Transcript at 1173:20–1174:13; 03/30/2022 Trial Transcript at
 11 1611:2–1613:7; 04/20/2022 Trial Transcript at 3249:7–3250:5. After Dr. Rosendorff resigned in
 12 November 2014, Defendant hired his dermatologist, Dr. Sunil Dhawan, as the CLIA lab director and
 13 Defendant also hired Dr. Lynette Sawyer as a temporary co-lab director—neither of whom spent much
 14 time overseeing Theranos' CLIA lab. *See* 04/27/2022 Trial Transcript at 4080:23–4091:17; 05/11/2022
 15 Trial Transcript at 5531:23–5547:6.

16 In September 2015, Sarah Bennett, a surveyor from the Centers for Medicare and Medicaid
 17 Services' ("CMS"), arrived at Theranos to do the two-year re-certification for its CLIA lab and to
 18 investigate complaints CMS had received. 05/03/2022 Trial Transcript ("5/3 Tr.") at 4618:19–4623:23.
 19 Ms. Bennett testified that Defendant was not only present at the entrance conference between Theranos
 20 and CMS, but Defendant led the meeting from the Theranos side, took charge with the staff deferring to
 21 him, and presented a PowerPoint to CMS. *See* 5/3 Tr. at 4630:13–4632:4. Ms. Bennett also testified
 22 that, in that PowerPoint Defendant presented, Defendant was described to CMS as Theranos' Chief
 23 Operating Officer ("COO") and President, and "responsible for all CLIA lab business operations."
 24 5/3 Tr. at 4631:18–4639:7; TX 5830. In the same PowerPoint, an organizational chart showed
 25 Defendant above Dr. Dhawan as lab director, Langley Gee as Quality Control Manager, and other lab
 26 personnel. *Id.* On cross examination, Ms. Bennett reviewed Theranos' response to the 2013 statement
 27 of deficiencies the company had received and testified that she would expect the lab to follow their
 28 outlined response plan. 5/3 Tr. at 4718:22–4726:11. Similarly, Ms. Bennett testified that Theranos

provided to CMS on or before April 1, 2016, in response to its January 2016 statement of deficiencies, a patient impact summary, with notice to the Defendant in the letter. 5/10 Tr. at 5089:23–5094:6, 5130:16–5134:4 (discussing TX 4943). Finally, the jury has also heard testimony that Defendant’s effective last day at Theranos was May 11, 2016. 04/05/2022 Trial Transcript at 2160:9–2162:8.

In sum, the evidence admitted during *this* trial supports finding an evidentiary basis for Rule 801(d)(2) between Defendant and Theranos’ response in April 2016 to CMS’s findings of deficiencies in the CLIA lab.

Second, Defendant points to testimony from Dr. Das in the *Holmes* trial in an attempt to create some ambiguity about his role in preparing TX 4943 (Motion to Reconsider at 4–7), but Dr. Das’ testimony in full context shows the very involvement Defendant is trying to extinguish. Dr. Das testified in the *Holmes* trial that he was hired by Theranos in December 2015, but he was unable to work at Theranos full-time until mid-March 2016 because of obligations to his prior place of employment. *United States v. Holmes*, 11/09/2021 Trial Transcript (“11/9 Tr.”) at 5784:7–5785:10. Dr. Das testified that Defendant left Theranos “not too long” after Dr. Das joined in March—which is true given Defendant’s last day was May 11, 2016, as shown during this trial—and he understood that prior lab directors had reported to Defendant. *See* 11/9 Tr. at 5794:14–22; *United States v. Holmes*, 11/10/2021 Trial Transcript (“11/10 Tr.”) at 5913:19–5915:16. Nevertheless, shortly after Dr. Das began full-time at Theranos in mid-March 2016, he participated in a meeting with co-Defendant Holmes, Defendant Balwani, Daniel Young, and several lawyers from Boies Schiller Flexner LLP (“BSF”), where Dr. Das insisted that Theranos needed to void all tests run on the Edison 3.5 device. *See* 11/9 Tr. at 5824:15–5835:14 (discussing TX 4943); 11/10 Tr. at 5947:19–5948:6 (mentioning co-Defendant Holmes, Dr. Young, BSF attorneys, and “others”); *see also* ECF No. 893-2 at 3 (stating in February 2021 interview with federal agents that Defendant was present at the same meeting). Co-Defendant Holmes also elicited from Dr. Das on cross examination that, around that same time, Defendant Balwani was working with BSF lawyers in responding to questions from the *Wall Street Journal* regarding the deficiencies found in the January 2016 CMS report. *See* 11/10 Tr. at 5991:20–5992:23 (discussing TX 10628). Thus, the Court has a sufficient basis to conclude that Defendant was present at the meeting, and thus part of Theranos’ internal decision-making, where potential patient impact was

discussed by Dr. Das with Theranos' senior management—including Defendant—and Theranos' outside lawyers.

Furthermore, Defendant has repeatedly—and incorrectly—labeled TX 4943 regarding patient impact assessment as “authored” by Dr. Das. *See, e.g.*, 5/10 Tr. at 5095:21–23. But testimony and colloquy during the *Holmes* trial demonstrates the patient impact assessment was contributed to by many individuals at Theranos. For example, in objecting to its admission under Federal Rule of Evidence 702, co-Defendant Holmes' counsel noted that TX 4943 is “a compilation of patient impact assessments that are compiled *by Theranos* with Dr. Das's involvement[.]” 11/9 Tr. at 5714:13–21. When the government described the April 1, 2016 letter response to CMS as “from you[.]” Dr. Das corrected in his answer that it was “from Theranos.” 11/9 Tr. at 5799:8–5800:23. Defendant's motion, itself, makes a point of describing the letter and its analysis as from Theranos (rather than himself). *See* ECF No. 1487-2 at 6–7 n.3. Thus, the patient impact summary was *Theranos'* response, as a company, to CMS's January 2016 statement of deficiencies, at a time when Defendant was still the company's COO and fielding questions from the media about the same CMS deficiency findings, which could render it an adopted or authorized statement by Defendant under Rule 801(d)(2) or statements by an agent.

Third, to the extent the Court considers evidence beyond that presented in this trial, such evidence overwhelmingly supports a finding that Defendant was involved in the company's response to CMS's January 2016 findings and his responsibility for engaging with CMS did not diminish prior to May 2016. To list just a few examples:

- Immediately upon receiving the January 26, 2016 CMS report, Defendant convened a meeting to discuss “CMS Audit Responses,” assigned employees to tasks for the company's response, and shared a working copy of a Word document containing the company's draft response. Exhibit 1.³ He continued over time to supervise the response, including being directed in mid-February 2016 to the file folder where Theranos patient impact assessments were stored. Exhibit 2 at 4.
- In February 2016, when advised about patient impact for redraws, Defendant demanded a meeting and said he was “really irritated that these critical bugs are not escalating to me so I can put more resources and focus on this.” Exhibit 3.
- On March 2, 2016, when advised about plans for patient impact summaries, Defendant directed: “we should also put this in the context of other labs[;] you should have someone do a quick

³ All references to exhibits are those accompanying the Declaration of Kelly I. Volkar in Support of United States' Opposition to Defendant's Motion to Reconsider, filed concurrently.

1 search in the literature or consultants may know what % of lab results are corrected after the final
2 results are sent out.” Exhibit 4.

- 3 • On March 18, 2016, Defendant was among four Theranos senior officers to receive a letter from
4 CMS indicating CMS’ dissatisfaction with Theranos’ response to the Form 2567. Exhibit 5.
- 5 • Throughout March 2016, Defendant Balwani received working draft responses from the BSF
6 attorneys. See Exhibit 6 (March 7, 2016); Exhibit 7 (March 25, 2016).
- 7 • On March 25, 2016, Dr. Das discussed patient assessments within Theranos, CC’ing Defendant,
8 and indicated an intention to “VOID every run that fails Theranos-established QC rules.” Exh. 8.
- 9 • On March 30, 2016, Defendant and Dr. Das (but not Holmes) participated in a quality committee
10 whose agenda was to respond to “[i]tems from the inspection.” Exhibit 9 at 1. The agenda
11 included “TPS 3.5 shutdown.” Exhibit 9 at 2.
- 12 • On March 31, 2016, Ms. Bennett confirmed receipt of Theranos’ response and discussed options
13 for obtaining the corrected and voided reports, which Dr. Das forwarded to Defendant and others
14 outlining a planned response. Defendant approved the plan for transmission. Exhibit 10.

15 In sum, as the Court found in its Order, Defendant was COO of Theranos in April 2016 and he
16 held himself out to Ms. Bennett as the person responsible for the CLIA lab. ECF No. 1483. From the
17 evidence introduced in this trial, alone, the Court may conclude there was a sufficient agency
18 relationship for purposes of Rule 801(d)(2), or that Defendant adopted or authorized the admission, and
19 nothing from Dr. Das’ testimony in the *Holmes* trial undercuts that ruling, as the Court previously held.
20 Indeed, additional available evidence overwhelmingly demonstrates a sufficient evidentiary basis for
21 purposes of Rule 801(d)(2). For the foregoing reasons, the government respectfully requests the Court
22 deny Defendant’s Motion to Reconsider the Court’s order denying Defendant’s motion to strike portions
23 of Sarah Bennett’s testimony.

24 DATED: June 12, 2022

Respectfully submitted,

STEPHANIE M. HINDS
United States Attorney

/s/ Kelly I. Volkar
ROBERT S. LEACH
JEFF SCHENK
JOHN C. BOSTIC
KELLY I. VOLKAR
Assistant United States Attorneys